VII. 510(k) Summary

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title 21 of the Code of Federal Regulations Part 807 (21 CFR §807), and in particular §807.92, the following summary of safety and effectiveness information is provided:

A. Submitted for

AESCULAP®, Inc.
3773 Corporate Parkway
Center Valley, Pennsylvania 18034
Telephone: (610) 797-9300
Contact: Joyce Thomas, Director of Regulatory Affairs & Quality Assurance
Date Prepared: July 9, 2001

B. Device Name

Trade or Proprietary Name:	*PremiCron®* Nonabsorbable PET Surgical Suture
Common or Usual Name:	NonabsorbablePolyester Surgical Suture
Classification Name:	Nonabsorbable Poly(Ethylene terephthalate) Surgical Suture

C. Predicate Devices

The subject device is substantially equivalent to the following predicate devices:

- SURGIDAC® Nonabsorbable Surgical Suture (U. S. Surgical Corp.)
- ETHIBOND® Nonabsorbable Surgical Suture (Ethicon, Inc.)
- TI-CRON® Nonabsorbable Surgical Suture (Sherwood Davis & Geck)
- *Synthofil®* Nonabsorbable Surgical Suture (AESCULAP®)

D. Device Description

The subject device is an mutlifilament, nonabsorbable, sterile, flexible thread composed of 100% poly(ethylene terephthalate), or PET, and is indicated for soft tissue approximation and/or ligation, including cardiovascular, ophthalmic, and neurological tissue. It is available uncolored, or colored with D&C Green No. 6. It is available uncoated, or with a silicone coating. It is available with or without standard or detachable stainless steel needles.

E. Intended Use

PremiCron® Nonabsorbable PET Surgical Suture is indicated for use in general soft tissue approximation and/or ligation, including cardiovascular, ophthalmic, and neurological tissue.

F. Comparison to Predicate Devices

The subject device is composed of 100% poly(ethylene terephthalate) polymer, as is true of the predicate ETHIBOND®, TI-CRON®, SURGIDAC®, and *Synthofil®* sutures. As is also true of these predicate devices, the subject device is offered uncolored, or colored with D&C Green No. 6 at a concentration that conforms to the requirements of Title 21 CFR, §74.3206. Like TI-CRON® and other sutures, the subject device is offered with a silicone coating.

The subject device has the same design as do the ETHIBOND®, TI-CRON®, SURGIDAC®, and *Synthofil®* predicate devices, being a sterile, flexible braided multifilament thread.

As is true of the predicate sutures, the subject suture is offered in a variety of lengths and a range of diameters, and is offered with or without one of a selection of standard or detachable stainless steel needles. Further, as is the case with the predicate devices, the subject device conforms in all respects to the requirements of the Official Monograph for Nonabsorbable Surgical Suture in U.S.P. XXIV, including <861> *Sutures -- Diameter*, <871> *Sutures -- Needle Attachment*, and <881> *Tensile Strength*.

The subject device is manufactured in a manner typical of the industry and equivalent to that used to produce the predicate devices, wherein the poly (ethylene terephthalate) polymer is synthesized, and polymer is then melt extruded (colorant is added if desired) and spun to form fine filaments of specified diameter. These filaments are then "drawn" to enhance tensile properties, braided to form a fiber of the desired diameter, and where appropriate, coated with a lubricant to enhance handling properties and reduce tissue drag. The fibers are then cut to length and attached to needles.

As is true of the predicate ETHIBOND® sutures, *PremiCron®* sutures are offered with small "pledgets" of 100% TEFLON® polytetrafluoroethylene.

The subject device is packaged and sterilized in the same or equivalent manner, and has the same or equivalent labeling claims as do the predicate devices, including indications, contraindications, warnings, cautions and precautions.

G. Summary of Non-Clinical Tests

Non-clinical testing conducted on the subject device sterilization validation and evaluation of sterilant residues, shelf-life testing, and a series of state-of-the-art *in vitro* and *in vivo* assays to establish biocompatibility and *in vivo* behavior.

H. Summary of Clinical Tests

(Not applicable)

I. Conclusions of Non-Clinical and Clinical Tests

The results of testing demonstrated the substantial equivalence of the subject device in terms of its biocompatibility and *in vivo* behavior.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 9 2001

Aesculap, Inc.
c/o Mr. Steve Reitzler, RAC
Regulatory Consulting Services
13221 Maricotte Place
San Diego, California 92130

Re: K012201
Trade/Device Name: PremiCron® Nonabsorbable PET Surgical Suture
Regulation Number: 878.5000
Regulation Name: Nonabsorbable polyethylene terephthalate surgical suture
Regulatory Class: II
Product Code: GAT
Dated: July 9, 2001
Received: July 13, 2001

Dear Mr. Reitzler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walk, MD

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

V. Draft Labeling

A. Indications for Use

510(k) Number (if known): K012201

Device Name: AESCULAP®, Inc. *Monosyn®* Synthetic Absorbable Suture

Indications for Use:

PremiCron® *Nonabsorbable Surgical Suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular and vascular, ophthalmic and neurological procedures.*

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

510(k) Number K012201